



July 16, 2018

Mr. Andrew Wheeler
Acting Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comment on Proposed Rulemaking titled “Strengthening Transparency in Regulatory Science,” Docket ID No. EPA-HQ-OA-2018-0259

Dear Acting Administrator Wheeler:

The American Association for the Advancement of Science (AAAS), the largest general scientific society in the United States and the world, is writing to submit our views on EPA’s proposed rule, *Strengthening Transparency in Regulatory Science* (Docket ID No. EPA-HQ-OA-2018-0259). We appreciate that EPA extended the comment period for additional time to review and comment. In sum, AAAS strongly believes that the proposed rule would undermine EPA’s ability to use the best available science, and sends a chilling message to the general public and the scientific community that the agency would restrict the use of science in its decisions. AAAS recommends that the EPA rescind this proposal in its entirety for reasons outlined below.

As the publisher of the world’s preeminent peer-reviewed scientific journal *Science*, we are committed to upholding the values of scientific peer review and to ensuring, to the maximum extent possible, the quality of information in support of the conduct of research and the dissemination of research results. In response to EPA’s proposal, several peer-reviewed scientific journals, including *Science*, issued a joint statement noting that journal editorial standards “recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all data be fully shared.” The latter include private and confidential data that are protected under current laws and regulations already in place.ⁱ It further warns the agency that it “does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather it is paramount that the full suite of relevant science vetted through peer review...inform the landscape of decision making.”ⁱⁱ

The complexity surrounding access to scientific data utilized in regulations and policies deserves a thoughtful and rigorous discourse among the entities and stakeholders that comprise the public and private scientific community. AAAS is very concerned that EPA’s proposed rule will prevent the use of the best available scientific studies in setting critical public health and environmental policies in cases where the underlying data cannot or should not be made publicly

available. If put into practice, the proposed rule will prohibit the agency from using a wide swath of high-quality, past and present scientific research.

First, “secret science” does not lurk behind EPA’s decision making. The science used at EPA includes the release of necessary data for review – except those data prohibited from full disclosure under law, including protected health information such as the personal information of study participants. Second, there exist federal guidelines that provide access to and ensure the quality of scientific information used for federal policies and regulation which also emphasize the necessity to maintain needed privacy or assurance of suitable confidentiality.ⁱⁱⁱ Furthermore, there are credible procedures for testing results and verifying outcomes with methodologies that do not require access to raw data. There are also procedures for providing protected, limited access to the full raw data to independent researchers for independent validation without making the full data publicly available. These procedures negate the need for this proposed rule, as they respect privacy laws and bona fide practices used by the scientific community.

Requiring all raw data to be made publicly available before a study can be utilized in EPA decision-making will cut off EPA from foundational research that has informed EPA’s work since the inception of the agency and may violate Federal laws and directives already in place. The proposed rule sets an implied standard that peer-reviewed scientific research data that is not publicly available is not rigorous enough for use in decision making. As mentioned above and articulated by numerous science and health organizations, many health studies, especially those that uncover the effects of exposure to toxins and pollutants, rely on medical records that are sensitive covered information, and are confidential and private based on federal law and other patient privacy policies. In preparing these studies for peer review and publishing, researchers summarize the analysis of raw data and draw conclusions based on that analysis—methodologies that are not ‘secret’ but rather common practice.

While epidemiological studies often contain patient information and must maintain individual privacy, other studies may rely on public and private-sector funding sources that limit access to underlying data for proprietary reasons. The EPA’s proposed rule risks rejecting this valid scientific evidence and fundamentally mischaracterizes the way science is conducted and made available for decision-making. By limiting the science EPA can use in policies and regulations, EPA will ultimately constrain itself to smaller groups of studies and risk biased outcomes. If the pool of research is smaller – which is what this proposed rule will lead to – that smaller pool utilized creates an inherent bias and thus the rulemaking process will yield distorted results.

This very concerning outcome becomes apparent in the section of the proposed rule titled “Public Availability of Data and Models.” Here the EPA notes that it is seeking greater transparency and public access to “dose response data and models underlying pivotal regulatory science.” Access to these data and models are also expected to be made available in a “fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security.” The problem is that these two statements are incompatible. EPA cannot have access to dose response data and models that are by law protected. Therefore, the rule is concerning as it cannot comport with current laws protecting privacy. Thus, it ultimately limits the use of science containing legally protected data, much of which is specifically conducted to protect health and the environment.

Moreover, the agency asks whether to add stronger data access requirements to the terms of research grants. AAAS believes it would be premature to introduce additional changes to the terms of research grants until the full impacts of any proposed EPA transparency policy are understood.

Regarding the “Role of Independent Peer Review” section, AAAS appreciates the recognition of independent peer review and the importance of complying with OMB’s Final Information Quality Bulletin for Peer Review (70 FR 2664). However, the proposed rule states that EPA will ask peer reviewers to articulate the strengths and weaknesses of EPA’s assumptions, implying that the agency would be implementing a separate and secondary level of peer review to address assumptions. Furthermore, the proposal does not articulate whether the “peer reviewers” would be the same peer reviewers or scientific advisory committee that conducted the original scientific assessment. This introduces an unnecessary phase of peer review that risks introducing regulatory inertia and the ability of the agency to utilize the best available science in its decision-making.

Regarding prospective and retrospective application, while the proposed rule states that it will be prospectively applied to future regulations and policies, it acknowledges it will capture scientific data and models that were developed prior to this current proposal. AAAS believes that all prior studies should be exempt from this rule, as many foundational studies regarding air quality and asthma and exposure to mercury and lead were conducted decades ago. Thus, it will be difficult or impossible to make all the underlying data fully accessible. Most of these studies have been reanalyzed, reassessed and/or reproduced by other institutions and countries. Applying this rule to science retroactively would be impractical and once again narrow the scope of scientific research available to the agency.

On the section of the proposed rule giving the EPA Administrator sole authority to grant exceptions to the rule, AAAS believes this kind of authority does not provide for proper checks and balances with appropriate oversight bodies. Since the agency addresses a wide range of scientific disciplines that intersect with the environment and public health, this exemption would eliminate the important role that relevant scientific advisors should play in the decision-making process.

In conclusion, it has been recognized since 2002 by the D.C. Circuit Court that it would be “impractical and unnecessary” for the EPA to require that all underlying data be made public.^{iv} The court recognized the importance of EPA to have access to as much scientific information as possible to protect public health and the environment.

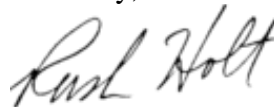
Regulations and agency actions do indeed need to be informed by the best available science and a rigorous scientific process. It is for this reason that AAAS opposes issuing a policy that would restrict the ability of a federal agency to utilize rigorous science as it establishes policies and that could have long-term, negative consequences to public health and the environment for all Americans.

AAAS recommends that EPA withdraw this proposed rule until a more thorough examination by an independent scientific organization can be completed on the impacts that the policy would have on the agency's ability to access the best available science in its rulemaking.

Throughout its history, EPA has accomplished its mission by carefully managing transparency, scientific rigor, protection of sensitive information, and evidence-based decision-making under an array of environmental and other laws. These practices have worked well in ensuring that EPA relies on the best available science in its decision-making. There is always room for improvement. Indeed, over the past few years EPA has embarked on several initiatives that enhance access to and transparency of data and science used to inform agency decisions. But there remain cases when the transparent and proper use of the best available science requires that some of the underlying data cannot be made publicly available for legitimate reasons.

AAAS urges EPA to consider carefully and deliberately, in concert with the scientific community and other stakeholder communities, any policy changes that could diminish the important role of scientific evidence in helping to make decisions that impact the health of Americans.

Sincerely,



Rush D. Holt
CEO and Executive Publisher

ⁱ IRB policies 45 CFR Part 46, <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>; Federal Policy for Protection of Human Subjects, Fed Reg 56:117, <https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>; NIH Policy for Issuing Certificates of Confidentiality, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>; 21st Century Cures Act, (Public Law 114-255), <https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf>

ⁱⁱ Berg, J., Campbell, P., Kiermer, V., Raikhel, N., Sweet, D. Joint statement on EPA proposed rule and public availability of data. *Science*. 2018 May 4:360(6388).
<http://science.sciencemag.org/content/early/2018/04/30/science.aau0116>.

ⁱⁱⁱ Part IX OMB Fed Reg 67:36, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies."

^{iv} <https://law.justia.com/cases/federal/appellate-courts/F3/283/355/484491>